Remarks

I. Claims Status

Prior to this amendment, claims 1-13 were pending. Claims 2-8, 10, 12 and 13 have been cancelled without prejudice. Claim 1 has been amended to delete X as S; restrict R^1 to quinoxaline or substituted quinoxaline, and restrict R^3 and R^4 to non-heterocyclic groups (the Examiner also mentions R^6 however there is no R^6 present). Support for R^1 being quinoxaline is found in the application as filed at page 13 lines 1-3 and example 3 on page 40 lines 26-29. Claim 9 has been amended to delete redundant language based on the amendments to claim 1.

New claims 14 and 15 have been added. Claim 14 is directed to the compound in Example 3 or a pharmaceutically acceptable salt thereof. Support may be found in the application as filed at page 40 lines 26-29 and page 16 lines 1-14. Claim 15 is directed to a pharmaceutical composition comprising the compound in Example 3 or a pharmaceutically acceptable salt thereof. Support may be found in the application as filed at page 40 lines 26-29, page 16 lines 1-14 and page 13 lines 9-10.

No new matter has been added by these amendments.

II. Claim Rejections

a) 35 U.S.C. § 112 First Paragraph

Claim 1 stands rejected under 35 U.S.C. § 112 first paragraph. The Examiner contends that the prodrugs and solvates of the compounds of the invention are not enabled. Applicants respectfully traverse this rejection. Applicants submit that prodrugs and solvates of the compounds of the invention are enabled and have been generally described. The test for enablement is whether one reasonably skilled in the art could make and use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. Applicants submit that based on this extensive teaching of the present specification a person of ordinary skill in the art can readily select any number of appropriate prodrug moieties to form prodrugs of the compounds of the invention, or in the case of solvates, recrystallization or chromatographic solvents to form solvates of the compounds of the invention upon recrystallization or evaporation. Applicants specifically point to the specification as filed at page 35 lines 1-31 and page 36 lines 1-3 for description of various prodrugs. It is contended that one of reasonable skill would be able to choose prodrug

moieties compatible with the structure of the compound of the invention based on the information in the specification and information known in the art without undue experimentation.

The Examiner in analyzing the Wands factors appears to be basing a significant part of her argument on stability and interconversion of one form into another (either prodrug or solvate) during manufacture. Applicants respectfully argue that the Examiners analysis is misplaced. In order for a prodrug to fulfill its intended function it would have to be stable to most conditions except for metabolism in the body as pointed out in the specification at page 35 lines 3-17. The prodrug moieties taught in the specification coupled with what is known in the art would enable one of reasonable skill to synthesize prodrugs that are stable except for metabolism in the body.

Solvates are crystalline or amorphous forms of compounds where solvent molecules have been trapped within the crystalline lattice structure or within the amorphous solid. Solvent molecules may in some cases be driven off upon standing, heating or under reduced pressure or a combination of heating and reduced pressure. The formation of solvates requires only some solubility of the compound in a solvent followed by recrystallization or reduction in vacuo. It is therefore contended that given the teaching of the specification coupled with what is known in the art would enable one of reasonable skill to synthesize solvates. The long or short term stability of the solvate or its stability during manufacture of the formulated drug is not relevant to the question of enablement.

Applicants respectfully request reconsideration and withdrawal of this rejection.

b) 35 U.S.C. § 112 Second Paragraph

Claim 1 stands rejected under 35 U.S.C. § 112 second paragraph. The Examiner contends that the terms "prodrug" and "solvate" in claim 1 are indefinite. Applicants respectfully traverse this rejection. The test for indefiniteness is whether those skilled in the art would understand what is being claimed. The term "prodrug" is a known term of art which is defined in the specification at page 35 lines 3-10. Solvates are a known term of art which is defined as a crystalline or amorphous form of a compound which contain a certain amount of a solvent. It is therefore contended that one of reasonable skill would know and understand what is being claimed and therefore the terms are not indefinite. Reconsideration and withdrawal of this rejection is respectfully requested.

Conclusion

It is believed that the application is now in condition for allowance. Favorable action is earnestly solicited. If the Examiner believes a telephonic interview would expedite the prosecution of the instant case she is invited to call the applicants representative whose contact information appears below.

Please charge the $130.00 fee due under 37 C.F.R. §1.20(d) to Deposit Account No.16-1445. The Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment, to Deposit Account No. 16-1445. Two (2) copies of this sheet are enclosed herewith.

Date: March 9, 2005

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